

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re: Rosuvastatin Calcium Patent Litigation

)
) C.A. No. 08-md-1949-JJF
)
) **PUBLIC VERSION**
)

**DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
THEIR MOTION TO EXCLUDE THE EXPERT TESTIMONY OF MAMI HINO**

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Defendants Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc., on behalf of all Defendants in the above coordinated actions (collectively, "Defendants"), respectfully submit this Memorandum in support of their Motion to Exclude the Expert Testimony of Mami Hino, offered by Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively, "Plaintiffs"). As demonstrated in this memorandum, and the accompanying Declaration of Payson LeMeilleur submitted herewith, the Court should exclude Ms. Hino's testimony under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) and Fed. R. Evid. 702.¹

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Although Ms. Hino is offered as a patent law expert, most of her "opinions" are arguments, assumptions and inferences [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Accordingly, the only remaining issue for inequitable conduct based on this conduct is the sufficiency of Defendants' evidence that Ms. Kitamura and her colleagues acted with intent to deceive the PTO.

¹ Unless indicated otherwise, all citations to "Ex." refer to the exhibits attached to the LeMeilleur Declaration.

With respect to intent, Plaintiffs know what Shionogi's documents say and what Ms. Kitamura and her colleagues admitted in deposition. And because they know how damaging the factual record is, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

This Court and courts around the country uniformly reject such state-of-mind expert testimony as lacking "fit" or helpfulness to the trier of fact, and lacking reliability or scientific

basis. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ms. Hino has nothing to offer this Court as to governing U.S. law. The prosecution histories of the patent applications, and other related documents, speak for themselves. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

II. STATEMENT OF FACTS

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In addition, it is undisputed that the Sandoz application was cited to Shionogi in a formal prior art search report by the European Patent Office as a “particularly relevant” reference to Shionogi’s European counterpart to the ‘440 application. [REDACTED]

[REDACTED] Nevertheless, Shionogi pursued and obtained issuance of the ‘440 patent without disclosing either reference to the PTO.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Shionogi then sought and obtained a narrower reissue of the ‘440 patent after disclosing, *inter alia*, the Bayer and Sandoz prior art to the PTO, which led to the patent-in-suit. Ex. 5 (Information Disclosure Statement filed with reissue application). In order to meet the requirements for reissue, Shionogi represented to the PTO that it had claimed more

[REDACTED]

than that to which it had been entitled in view of prior art. Ex. 6 (Reissue declaration filed with reissue application). In addition to inequitable conduct during prosecution of the original ‘440 application, Defendants contend that Shionogi obtained its reissue patent by falsely representing that it had “erroneously” or “mistakenly” claimed inventions to which it had not been entitled in view of prior art. Indeed, Shionogi had intentionally claimed what was in the prior art, having concealed it from the PTO in order to do so.

[illegible]

[illegible]

[REDACTED]

.....

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[REDACTED]

[REDACTED]

Unwilling to rely on the Court's assessment of their own witnesses' testimony and credibility as to intent to deceive the PTO, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

III. ARGUMENT

A. The Court Should Exclude Proffered Expert Testimony That Lacks Qualification, Reliability And Fit Under Rule 702

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony, subject to the relevancy provisions of Rules 401 through 403. Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles

and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Proponents of expert testimony have the burden of establishing admissibility under Rule 702 by a preponderance of the evidence. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10 (1993). The Third Circuit has held that “[r]ule 702 embodies three distinct substantive restrictions on the admission of expert testimony: qualification, reliability, and fit.” *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3rd Cir. 2000); *see also In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-43 (3rd Cir. 1994).

With respect to qualification, the District Court must first determine whether the proposed expert is qualified by “knowledge, skill, experience, training, or education.” *Daubert*, 509 U.S. at 588.

The reliability restriction requires an expert’s opinion to “be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation’; the expert must have ‘good grounds’ for his or her belief.” *Paoli*, 35 F.3d at 742 (quoting *Daubert*, 509 U.S. at 590). Courts in the Third Circuit weigh several factors when evaluating whether a particular expert opinion is reliable, including:

(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Elcock, 233 F.3d at 745-46 (*citations omitted*). Where the proffered expert has performed no reliable testing of his or her theory, courts in the Third Circuit have routinely precluded the witness from offering an expert opinion. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145-46 (3rd Cir. 2000); *Elcock*, 233 F.3d at 748.

Lastly, the “fit” restriction “goes primarily to relevance” and “requires that the evidence or testimony ‘assist the trier of fact to understand the evidence or to determine a fact in issue.’” *Daubert*, 509 U.S. at 591. The “fit” requirement demands that the expert’s testimony contribute something to the trier of fact’s consideration that it could not itself supply. Courts routinely reject expert testimony that “constitutes mere personal belief as to the weight of the evidence and invades the province of the fact finder.” *Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 435 (D. Del. 2004).

[illegible]

[REDACTED]

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[REDACTED]

[REDACTED]

Under *Daubert*, however, Courts routinely exclude proposed expert testimony that expressly or impliedly addresses intent, motive or state of mind. *See AstraZeneca LP v. TAP*

Pharm. Prods., Inc., 444 F. Supp. 2d 278, 293 (D. Del. 2006)³ (“Expert witnesses are not ‘permitted to testify . . . regarding [the defendant’s] intent, motive or state of mind, or evidence by which such state of mind may be inferred.’”) (quoting *Oxford*, 345 F. Supp. 2d at 443 (excluding expert testimony regarding what accused patent infringer “recognized,” “felt,” and “concluded”)); see also *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 440-441 (D.N.J. 2009) (excluding expert opinion on intent such as what defendant was “trying to do with its marketing strategy and what it believed was right or wrong”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 545-47 (S.D.N.Y. 2004) (“Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony.”); *Tap Pharm. Prods., Inc. v. Owl Pharms., LLC*, No. 1:99 CV 2715, 2003 WL 25695241, at *1 (N.D. OH Feb. 18, 2003) (“The question of intent is one for the court to decide; it is therefore not a subject suitable for expert testimony.”).

Additionally, such testimony goes beyond the limited role, if any, patent law experts have at trial in this Court. See, e.g., *Lucas Aerospace, Ltd. v. Unison Indus., L.P.*, C.A. No. 93-525-MMS, 2008 WL 5868690, at *1 (D. Del. Sept. 30, 2008); *Proctor & Gamble Co. v. Teva Pharms. USA, Inc.*, C.A. No. 04-940-JJF, 2006 U.S. Dist. LEXIS 54260, at *2-4 (D. Del. Aug. 4, 2006); *LP Matthews LLC v. Bath & Body Works, Inc.*, 458 F. Supp. 2d 198, 210 (D. Del. 2006) (citing the Court’s Guidelines on Legal Expert Testimony in Patent Cases); Ex. 10 (Delaware Guidelines). Thus, Ms. Hino’s testimony is improper and should be excluded for this reason alone.

³ Indeed, it would be hard to find a litigant who is more keenly aware of this law than Plaintiff AstraZeneca in this case, as AstraZeneca cited the same authority in persuading this Court to exclude the same type of expert evidence of intent offered against it in *AstraZeneca*, 444 F. Supp. 2d at 293.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Thus, Ms. Hino's testimony is unhelpful, irrelevant, a waste of time and, in fact, misleading in view of the direct evidence from Ms. Kitamura. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

As an initial matter, Ms. Hino's discussion of Japanese patent law here is not relevant to any issue in the case, and should be excluded on that basis alone. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

Moreover, to the extent Ms. Hino's testimony seeks to invade the province of the Court's inequitable conduct determination at all, such testimony is improper and should be excluded. *See Revlon Consumer Prods. Corp. v. L'Oreal S.A.*, No. 96-192-MMS, 1997 U.S. Dist. LEXIS 4117, at *9-10 (D. Del. Mar. 26, 1997) (excluding expert testimony regarding inequitable conduct because allowing such testimony "would usurp the respective functions of the jury and the Court"); *Argus Chem. Corp. v. Fibre Glass-Evercoat Co.*, 759 F.2d 10, 13 (Fed. Cir. 1985) (expert testimony regarding inequitable conduct irrelevant); *see also Intermatic Inc. v. Lamson & Sessions Co.*, No. 94-C-50295, 1999 U.S. Dist. LEXIS 4022, at *3 (N.D. Ill. Mar. 30, 1999) (excluding expert testimony regarding inequitable conduct as irrelevant).

[illegible]

[REDACTED]

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For this

reason, Courts routinely exclude testimony that consists of an expert simply reiterating the contents of documents as unhelpful and unnecessary, [REDACTED]

[REDACTED] *Ondeo Nalco Co. v. Eka Chems., Inc.*, No. 01-537-SLR, 2003 U.S. Dist. LEXIS 4437, at *9-10 (D. Del. Mar. 21, 2003) (striking expert report and testimony where witness “‘walks through’ the file history of the [patent-in-suit] and opines as to how the United States Patent and Trademark Office would have responded had certain prior art been disclosed to it”); *see also Bausch & Lomb, Inc. v. Alcon Lab., Inc.*, 79 F. Supp. 2d 252, 256 (W.D.N.Y. 2000) (excluding expert testimony that merely outlines the prosecution history because such evidence can be presented through documents and fact witness testimony); *Rezulin*, 309 F. Supp. 2d at 551 (excluding expert testimony consisting of a narrative of factual events because “[s]uch material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence”); *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 468-69 (S.D.N.Y. 2005) (“To the extent [an expert] is simply rehashing otherwise admissible evidence about which he has no personal knowledge, such evidence-taken on its own-is inadmissible...[A]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence.”).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See Ex. 10 (Delaware Guidelines); *Proctor & Gamble*, 2006 U.S. Dist. LEXIS 54260, at *3 (“This Court excludes testimony by patent law experts on substantive issues of patent law.”) (citing *Revlon*, 1997 U.S. Dist. LEXIS 4117, at *9-10 (excluding expert testimony regarding substantive issues of patent law such as the “duties and responsibilities of an inventor, his or her attorney or agent, and others substantively involved in the preparation and prosecution of a patent application in the PTO....”))).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ex. 10 (Delaware Guidelines); *Proctor & Gamble*, 2006 U.S. Dist. LEXIS 54260, at *3; *Revlon*, 1997 U.S. Dist. LEXIS 4117, at *9-10.

IV. CONCLUSION

Based on the forgoing, Defendants respectfully request the Court exclude the expert testimony of Mami Hino pursuant to *Daubert* and Rule 702.

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FILED ON BEHALF OF ALL DEFENDANTS

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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I, David E. Moore, hereby certify that on September 30, 2009, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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